Statement of Ranking Member Frank Pallone, Jr.
House Committee on Energy and Commerce
Subcommittee on Health
"Examining Improvements to the Regulation of Medical Technologies"

May 2, 2017

Thank you, Mr. Chairman. Today we are examining additional legislation that will help to improve the way the Food and Drug Administration reviews medical device products.

Medical devices have made enormous advances over the last few decades, and new and emerging technologies hold the promise to treat and cure diseases in ways previously not thought of. While not the subject of today's hearing, reauthorizing the Medical Device User Fee Amendments will help to ensure that FDA has the resources and personnel needed to continue to improve upon the medical device review process and to work with industry to bring devices to market more efficiently. I look forward to working with my colleagues to have all of the user fee agreements considered and sent to the President early this summer.

I understand that Members are interested in exploring the possibility of attaching additional policy to the user fee agreements. This hearing provides the opportunity to learn more about whether these bills meet the test of being non-controversial and enjoying broad bipartisan support.

Today we will be hearing from our witnesses about the following four bills:

- H.R. 1652, sponsored by Representatives Kennedy, Blackburn, and Carter, would direct FDA to establish by regulation a category of over-the-counter hearings aids for adults with perceived mild to moderate hearing loss. This bill could open up access to affordable hearing aid devices for the more than 37 million American adults who suffer from hearing loss today.

- H.R. 2009, sponsored by Representative Peters and Costello, would clarify the FDA review process for new indications of contrast agents used with medical imaging devices.

- H.R. 2118, also sponsored by Representative Peters and Costello, would require third party service providers of medical devices to register with the FDA, maintain a complaint handling system, and submit adverse event reports as original equipment manufacturers do today.

- And finally, H.R. 1736, sponsored by Representatives Peters, Butterfield, Buschon, and Brooks, would move FDA inspections of medical device facilities to a risk-based schedule, and would improve communication between FDA and industry throughout the inspection process.

I look forward to learning more from Dr. Shuren, as well as our other stakeholders, about their interests in the legislation before us.